REMARKS

Claims 1-19, 25, 27, 29-37, 39-45, and 47 are pending. Claims 1, 25 and 44 are amended; support for the amendments can be found in the specification at, for example, pages 8 and 21-22 . Claim 27 is amended to correct a typographical error. No new matter has been added.

Claim objection

Claims 27 and 29 were objected to for improperly depending from a canceled claim. Office Action at 2. Claim 27 has been amended to depend from pending claim 25. Claim 29 depends from claim 27. Applicants respectfully ask that the objection be withdrawn in view of the amendment.

Rejections under 35 U.S.C. § 102

Stapleton

Claims 1-5, 8-15, 17-19, 25, 27, 29-30, 34-36, and 39-45, and 47 have been rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,922,604 to Stapleton et al. ("Stapleton"). Office Action at 3. Claims 1, 25, 44, and 48 are independent. Claim 1 relates to a device having a continuous cavity that forms a single reaction chamber that is adapted to amplify **and** characterize nucleic acids **almost simultaneously** therein.

Claim 25 relates to a device having a continuous cavity that is adapted to act as a single chamber for **almost simultaneous** reaction and characterization of nucleic acids.

Claim 44 relates to a device having continuous cavity that consists of a single chamber for **almost simultaneous** reaction and characterization of nucleic acids such that only the single chamber holds the nucleic acids for both reaction and characterization.

Each of independent claims 1, 25 and 44 relates to a device having a chamber body including an optically permeable chip. Stapleton does not describe a chamber body that includes an optically permeable **chip**, where there is an array of multiple different polynucleotide probes immobilized on the optically permeable chip.

The chip is a distinct element of the device, which includes:

- an chamber support;
- an optically permeable chip on which polynucleotide probes are immobilized; and
- a chamber body containing or including the chip.

See claim 1, and the specification, e.g., at 7 and 11, and FIGS. 1-2, illustrating the relationship of chamber support, chip, and chamber body. In particular, the chip is "held by chamber body 1 through the edge 42 thereof" (see FIG. 2). The specification explains at 11-12 that the chip can be, for example, silicon or glass, whereas exemplary materials for chamber body include glass, nylon, PMMA, Teflon, polycarbonate, polystyrene, and topaz. The different choices of materials for the two elements reinforces the conception of chip and chamber body as distinct elements.

In contrast, Stapleton describes a device having only two elements: a base and a cover. See, e.g., col. 5, line 64 to col. 6, line 9, and FIG. 1. The microprobe array is immobilized on either the base or the cover (col. 5, lines 40-44). Nothing in Stapleton indicates that an array is immobilized on a third element, i.e., a chip distinct from the base and cover. For at least this reason, claims 1, 25 and 44 and the claims that depend from them not anticipated by Stapleton.

Each of independent claims 1, 25 and 44 relates to a device having a single reaction chamber. The single reaction chamber is either adapted to amplify and characterize nucleic acids **almost simultaneously** therein (claim 1) or for **almost simultaneous** reaction and characterization of nucleic acids (claims 25 and 44).

The Examiner argues with respect to claims 1, 25, and 44, that Stapleton teaches a device having "a continuous cavity [that] forms a single reaction chamber adapted to amplify and characterize nucleic acids therein (Column 10, line 1-27 and Column 14, lines 40-57)." See the Office Action at pages 4, 5 and 7. Applicants respectfully disagree.

Stapleton relates generally to thin reaction chambers for containing and handling microvolumes (Title). Stapleton discusses design features for limiting bubble formation during thermocycling (col. 10, lines 1-27). Elsewhere, in a different context, Stapleton indicates that the device can include an array. Stapleton notes that "the device is capable of processing samples with different liquid treatments such as needed for labeling and hybridizing nucleic acid

samples." (col. 14, lines 50-52). However, Stapleton never indicates or even hints that the two different functions--thermocycling and hybridizing--can be performed **almost simultaneously** in **a single reaction chamber**. In other words, Stapleton doesn't teach a device that includes all of the claimed limitations, most particularly, a **single** reaction chamber that is adapted to amplify **and** characterize nucleic acids **almost simultaneously** therein (as in claim 1), or a **single** chamber for **almost simultaneous** reaction and characterization of nucleic acids (as in claims 25 and 44). In fact, Stapleton indicates that in those instances when both functions may be performed, they are spatially separated:

> The device of the invention has working areas coated with reactants and therefore is suitable for preparing a microsample of a few specimen cells, amplifying, releasing or labeling targets nucleic acid sequences of the specimen to hybridize with **an oligo probe array on another coated working area**, for visual or instrumented detection.

(emphasis added) (col. 14, lines 58-63). Stapleton's array is not in the same reaction chamber where amplifying occurs.

The device described by Stapleton is not adapted so that reaction and characterization can occur almost simultaneously. See, for example, col. 3, lines 34-35 ("features are described which enable reagents to be **serially** added to, and removed from the working space"); and col. 8, lines 19-49 (discussing washing of liquids into a reaction chamber; "[t]he process is a simple way to effectively **change liquids** in a thin chamber"). Serial addition and removal of reagents, and the changing of liquids within the chamber are both inconsistent with a device capable of almost simultaneous reaction and characterization of nucleic acids.

For at least these reasons, claims 1, 25, 44, and 48, and claims that depend therefrom, are patentable over Stapleton. Reconsideration and withdrawal of this rejection is respectfully requested.

Besemer

Claims 25, 27, 29, 30, 44, 45, and 47 have been rejected as being anticipated under 35 U.S.C. § 102(b) by WO 95/33846 to Besemer et al. ("Besemer"). See the Office Action at page 8-12.

Besemer relates to "packaging devices for a substrate having an array of probes fabricated thereon." (page 5, lines 37-39). The Examiner argues that Besemer teaches "a continuous cavity [that] forms a single reaction chamber adapted for reaction (e.g. hybridize) and characterize (e.g. sequence) nucleic acids therein (page 20, lines 23-31)." See the Office Action at page 9.

At 20-21, Besemer describes how the chip package "will be useful in sequencing genetic material by hybridization." The Examiner here draws a spurious distinction between the hybridization and sequencing discussed by Besemer. In sequencing by hybridization, a variety of oligonucleotide sequences (i.e., probes) are allowed to hybridize with a target polynucleotide of unknown sequence. Stringent hybridization conditions allow only those sequences having perfect base pair matches to hybridize. Determination of the sequence of the unknown polynucleotide becomes simply a matter of deduction based on the results of the hybridization. In other words, Besemer describes a device for carrying out hybridizations without any chemical reaction or alteration of the oligo- or polynucleotides. Thus, Besemer fails to teach that the device has a continuous cavity adapted to act as a single chamber for **almost simultaneous** reaction and characterization of nucleic acids.

Therefore, 25, 27, 29, 30, 44, 45 and 47, are patentable over Besemer. Applicants respectfully request that the Examiner reconsider and withdraw the rejection.

Rejections under 35 U.S.C. § 103(a)

McBride

Claims 6 and 7 have been rejected under 35 U.S.C. § 103(a) as being obvious over Stapleton in view of U.S. Patent No. 6,296,752 to McBride et al. ("McBride"). See the Office Action at pages 10-11. Claims 6 and 7 depend from claim 1. Applicants respectfully disagree.

As discussed above, Stapleton fails to teach all the limitations of claim 1 (from which claims 6 and 7 depend). McBride does not remedy this defect. The combination of Stapleton with McBride does not teach, suggest or motivate a person skilled in the art to make the devices of claims 6 and 7. For at least these reasons, Applicants request that the Examiner reconsider and withdraw this rejection.

Fodor

Claims 16, 17, 37 and 38 have been rejected under 35 U.S.C. § 103(a) as being obvious over Stapleton in view of U.S. Patent No. 5,744,101 to Fodor et al. ("Fodor"). See the Office Action at pages 11-12. Claims 16, 17, 37 and 38 depend from claim 1. Applicants respectfully disagree.

As discussed above, Stapleton does not teach all the limitations of claim 1 (from which claims 16, 17, 37 and 38 depend). Fodor does not remedy this defect. The combination of Besemer or Stapleton with Fodor does not teach, suggest or motivate a person skilled in the art to make the devices of claim 16, 17, 37 or 38. For at least these reasons, Applicants request that the Examiner reconsider and withdraw the rejection over Stapleton in view of Fodor.

CONCLUSION

Applicants ask that all claims be allowed. Please apply any charges or credits to deposit account 19-4293.

Respectfully submitted,

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